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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,937	10/13/2004	Hubert Thoma	H-32407A	6977

1095 7590 02/28/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
YEBASSA, DESTA LETTA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,937	THOMA ET AL.	
	Examiner	Art Unit	
	Desta L. Yebassa	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made for the applicant's amendment filed on 11/14/2005

Claim Rejections - 35 USC § 112

1. Claims 29-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The expression "**with the proviso that said veterinary active ingredient are not mixed surfactant prior to coating said carrier material** " is not found in the specification as originally filed. Therefore, the added material is deemed to be new mater.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24 and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by McTeigue et al. (U.S. Patent No. 6,149,943).

Instant claim 1 requires a pellet or tablet which in turn comprises (1) animal feed and (2) particles of a carrier coated with active agent, which in turn coated with a taste-masking layer. McTeigue et al. disclose a particle tablets containing cellulose (substrate) and coated particles containing the pharmaceutically active ingredient and polymer having the mean particle diameter of about 160 to 220 microns (column 2, lines 35-50) wherein a carrier is coated with active agent which in turn coated with taste masking layer (see examples 1-6 column 6-9). Since instant claim 1 does not specify what compounds come under animal feed. Therefore, cellulose taught by McTeigue et al is deemed to come under this category.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 27, 33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al. alone (U.S. Patent No. 6,149,943).

McTeigue et al. has been discussed above.

McTeigue et al. does not teach specifically instant lysed yeast and veterinary in gradient benazepril. However, since McTeigue et al. teaches generic pharmaceuticals one of ordinary skill in the art use the compositions of McTeigue et al. for any pharmaceutical including the claimed class of compounds with reasonable expectations of successes with the guidance provided by McTeigue et al. McTeigue et al also does not teach vitamins be added in additives however, since McTeigue et al. teaches vitamins on column 3, lines 65, one of ordinary skill in the art would be motivated to add vitamins in additives, if desired, with the reasonable expectation of success. However Patel et al. and Kitamura et al disclose what McTeigue et al lacks.

Claims 26, 28, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al. (U.S. Patent No. 6,149,943) in view of Patel et al. (WO 01/37808 A1), Gasson et al. (U.S. Patent No. 5,763,251) and Kitamura et al. (U.S. Patent No. 3,917,510).

McTeigue et al. has been discussed above.

Patel et al. disclose a pharmaceutical composition having a solid carrier including a substrate and an encapsulation coat, being formed of different combinations of pharmaceutical active ingredients, seal coated by a polymer layer, and further coated

with the protective polymer layer (abstract, page 5, lines 15-25, and see working example 6 and 7 page 80-81). Patel et al. also disclose an active ingredients that can be any compound or mixture of compounds having therapeutic or other value when administrated to an animal, particularly to a mammal, such as drugs, nutrients, cosmeceuticals, diagnostic agents, nutritional agents, and the like (page 6, lines 10-150), suitable hydrophobic active ingredients such as anti-inflammatory agents, analgesics, anthelmintics, anti-bacterial agents, anti-viral agents, anti-fungal agents, anti-migraine agents, etc. (page 6, lines 30 and page 7, lines 5), suitable preferred hydrophobic active ingredients can be , for example, benazepril, albendazol, albuterol, amphetamine, etc. (page 8, lines 15-20 and page 9, lines 10). Patel et al. also teaches the substrate of the solid carrier compositions, which can be a powder or a multiparticulate, such as a tablet, a capsule, granul, a pellet, a bead, a microcapsule, a nanocapsule, a platlet. Such substrates can be formed of various materials for example sugars such as lactose, sucrose, dextrose, polysaccharides such as maltodextrin or dextrates, starches, cellulosics such as microcrystalline cellulose or hydroxymethyl cellulose etc (page 51, lines25 and page 52, lines 5). Furthermore, Patel et al. teaches surfactants such as anionic, cationic, non-ionic, and zwitterionic surfactants suitable for use in pharmaceutical compositions (page 16, lines 5); additives such as proteins and minerals suitable for use in pharmaceutical compositions (page 57, lines 15-25 and page 58, lines 15-25); preferred polymers such as shellac, acrylic polymer (methacrylic acid, cellulose derivatives (ethyl cellulose, methyl cellulose), polyvinyl polymer, etc.

suitable for use in pharmaceutical compositions (page 62, lines 5-25 and page 63, lines 5-15).

Gasson et al. disclose method of destroying pathogenic or food-contaminating bacteria in which such bacteria can be lysed with a lysine or a variant of such a lysine from a bacteriophage of such bacteria; any kind of food treated with such a preparation by addition or application to surfaces for example, animal food such as pet food, or cattle food; drinks such as water, milk, soft drinks; of cut, cooked meat, or poultry, soft cheeses; etc. (column 2, lines 20-45).

Kitamura et al. disclose method for lysis of yeast cell walls in an aqueous media by enzyme, which is capable of lysing the yeast cells thereby to lyse the yeast cell walls, which may be carried out on a large scale in many kinds of yeast produced for food, feed and other industrial purposes (column 1, lines 60-65). Kitamura et al. also disclose further examples (see examples 1-2 and 6, column 4, lines 15-35 and column 5, lines 35-45).

McTeigue et al. does not teach specifically instant lysed yeast and veterinary in gradient benazepril. However, it would have been obvious to one ordinary skill in the art to use the teaching of McTeigue et al. for the preparation of an animal medicine which contains the active ingredients that masks the taste since Patel et al. disclose a pharmaceutical composition having a solid carrier including a substrate and an encapsulation coat, being formed of different combinations of pharmaceutical ingredients such as benazepril; Gasson et al. disclose method in which bacteria can be lysed with a lysine including any kind of food for example, animal food such as pet food,

or cattle food as described above; and Kitamura et al. disclose method for lysis of yeast cell walls which may be carried out on a large scale in many kinds of yeast produced for food, feed and other industrial purposes. The prior art references, as combined teach the limitations of the instant claims.

Response to Arguments

Applicant's argument and amendment filed on 11/14/2005 have been considered but are not persuasive.

Applicant argues that in Patel et al. the layer containing the active pharmaceutical ingredient contains one or more surfactants, in contrast, in the presently amended claims the presence of surfactant was excluded. The new grounds of rejection teach these limitations. McTeigue et al. disclose the coated particle containing the pharmaceutically active ingredient and polymers that have the mean particle diameter about 160 to 220 microns with out surfactants (column 2, lines 35-50) and also see the teaching of McTeigue et al. that have been further demonstrated by working examples (see examples 1, 3, 5, and 6 column 7-9). In other way art known surfactant, sodium lauryl sulfate was added to the composition (see specification page 28, paragraph 1), which contradicts the applicant's arguments. Therefore, applicant's argument is not persuasive.

The prior art references, as combined teach the limitations of the instant claims. Thus the invention as whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made. The rejection of record is maintained.

Conclusion

Due to the new grounds of rejection, this action is made non-final.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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